## Remarks

Claims 1 and 23-28 are pending. By this amendment, Claims 1, 23 and 24 have been amended and Claims 25-28 have been cancelled. Claims 2-22 were previously cancelled without prejudice to or disclaimer of the underlying subject matter in a response filed October 25, 2004. Support for the foregoing claim amendments may be found throughout the specification, for example at page 71, lines 13-15, in the sequence listing, and in the original claims. No new matter enters by these amendments. Upon entry of the foregoing amendments, claims 1 and 23-24 are pending in the application.

### *1. New Matter Rejection*

Claim 27 stands rejected under 35 U.S.C. § 112, first paragraph as allegedly "[containing] subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Office Action at page 2.

The Examiner alleges that the "98% sequence identity evaluation parameter has not been found." Office Action, page 2. The Examiner further contends that "Applicants also did not point to written support for this parameter" and therefore constitutes new matter. *Id.* Applicants respectfully disagree.

In Applicants' Response dated October 25, 2004, Applicants cited as support for the amendments to the claims, *inter alia*, the Specification at page 73, lines 1-15. *See,* Second Revised Response to Office Action mailed December 2, 2003, at page 7. In the paragraph cited by the Applicants, the specification provides that "one or more of the nucleic acid molecules of the present invention share between 100% and 98% sequence

identity...." Specification at page 73, lines 9-11. As such, the amendment is fully supported in the specification, at least as pointed to by the Applicants in the previous response and does not constitute new matter.

Although Applicants disagree with the rejection, to facilitate prosecution claim 27 has been cancelled without prejudice to or disclaimer of the underlying subject matter. As such, the rejection of claim 27 for alleged new matter is moot and reconsideration and withdrawal of this rejection is requested.

***2. Lack of Utility Rejections under 35 U.S.C. §§ 101 and 112, First Paragraph***

***A. Rejection under 35 U.S.C. § 101***

Claims 1 and 23-28 stand rejected under 35 U.S.C. § 101 paragraph, for allegedly lacking "patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility." Office Action mailed December 2, 2003 at page 4. The Examiner states that this "rejection is maintained and reiterated from the previous office action, mailed 12/2/03, and additionally applied to newly added claims 23-28 for the reasons of record." Office Action at page 3. Claims 25-28 have been cancelled without prejudice to or disclaimer of the underlying subject matter, so Applicants will respond to the rejection only as it pertains to claims 1 and 23-24.

The Examiner has acknowledged that the specification describes "a plethora of enzymes with their corresponding activities." Office Action mailed December 2, 2003 at page 4. However, the Examiner contends that the "disclosed uses are generally applicable to broad classes of this subject matter," and the specification "lacks any specific or

substantial connection disclosure between the elected SEQ ID NO:5 and any of the described enzymes." *Id.* Applicants maintain their disagreement with these assertions.

It is well established that "when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 298 (Fed. Cir. 1983). The present specification describes many objectives that are met by the present invention. For example, the claimed nucleic acid molecules are useful for isolating a variety of agronomically significant genes, acquiring molecular markers, promoters, transcriptional regulatory elements, identifying polymorphisms, in expression assays, etc. *See, e.g.*, page 96, *et. seq.*, under the heading "Uses of the Agents of the Invention." The claimed nucleic acid molecules also find use in the reduction of endogenous protein expression through cosuppression and antisense applications. *See, e.g.* page 144, line 3 through page 146, line 14.

Many of these uses are directly analogous to the use of a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell or organism. Significantly, the utility of the microscope under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to identify and characterize other nucleic acid molecules within a sample, cell or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed nucleic acid molecules possess the requisite utility under 35 U.S.C. § 101.

In the present Office Action, as in the previous action, the Examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid mole-

cules. Rather the Examiner attempts to undermine the existing utilities by stating that "the disclosed uses are generally applicable to broad classes of this subject matter." Office Action mailed December 2, 2003 at page 4. In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. This position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stifung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result...").

Such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. Such a result is not only untenable, but requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 306 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 163 (1933). Thus, it must be the case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

As noted above, the claimed nucleic acid molecules have many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and locate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecules will identify a ***unique*** subset of related sequences. This subset of related sequences is specific to the claimed sequences and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this

specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit a ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic acid molecules exhibit the requisite utility under 35 U.S.C. § 101.

The Examiner also maintains that the claimed nucleic acid molecules lack utility because "further characterization of the claimed subject matter would be required to identify or reasonably confirm a 'real world' use." Office Action mailed December 2, 2003 at page 4. The Examiner argues that the claimed nucleic acid molecules lack utility because he "does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter. *Id.* However, Applicants respectfully submit that the specification provides ample connection between SEQ ID NO:5 and the disclosed enzymes. For example, the specification describes the isolation of nucleic acid molecules from young maize seedlings (V8 plant development stage) for the production of the SATMON009 cDNA library. *See, e.g.,* specification at page 193, line 14, through page 194, line 7. As such, these sequences may function in plant growth, quality, yield, and could also serve as links in important metabolic, developmental, and catabolic pathways. The specification also describes, as noted by the Examiner, that the sequence of the enzyme encoded by SEQ ID NO:5 shares a high percent sequence identity to sequences of other ribulose-bisphosphate carboxylase enzymes. *See, e.g.*, Table A, page 254. Other portions of the specification describe that SEQ ID NO:5 encodes a ribulose-bisphosphate carboxylase enzyme (*see, e.g.,* specification at page 26, lines 9-17, page 79, lines 20-22, and Table A, page 254). Contrary to the Examiner's assertion that "applicants have failed to specify even a single agronomically significant gene that has some

type of current available utility," such disclosure provides a sufficient connection between SEQ ID NO:5 and the disclosed encoded enzyme, ribulose-bisphosphate carboxylase.

The Examiner maintains, however, that "several references have been previously provided [which] clearly bring into question the usability of sequence similarity to support a function such as sequence similarity to establish the enzyme activity" Office Action at page 4. The Examiner has provided references supporting only the general controversy in the art regarding homology, but has not provided any support for the proposition that the claimed nucleic acid molecules would not work for the recited utilities; or that one skilled in the art would doubt that the claimed nucleic acid molecules would work for the utilities disclosed in the present specification. A broad assertion of "unpredictability" in the art is not sufficient to reject the claimed invention for lack of utility.

Applicants again note that it is standard practice to use nucleic acids of known sequence (*e.g.*, SEQ ID NO:5) to perform gene expression analysis using methods such as microarray technology. Knowing that an RNA corresponding to the claimed nucleic acid molecule is expressed under certain conditions or in certain tissues or at certain levels is in itself useful. For example, such information is useful to detect and compare expression changes in tissue samples taken from organisms grown under different conditions, *e.g.*, drought stress, cold stress, exposure to pathogens, or exposure to chemical compounds. SEQ ID NO:5 might be differentially expressed, for example, under one or more growth conditions that tend to induce expression changes of ribulose-bisphosphate carboxylase. *See, e.g.*, specification at page 49, line 12 through page 54, line 10. Microarrays allow rapid, simultaneous expression analysis of thousands of sequences, and thus, informative

*patterns* of expression are derived from the microarray expression data. For at least these reasons, Applicants respectfully submit that expression analysis is a **use** of SEQ ID NO:5 in a real world context. Applicants further submit that the specification teaches one of skill in the art how to use SEQ ID NO:5 for this purpose. *See, e.g.,* specification at page 117, line 12 through page 118, line 15 (describing use of SEQ ID NO:5 for microarray analysis of gene expression profiles).

The Examiner has provided no evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utilities and, as such, has not met the burden of challenging the disclosed utilities. *Cf. In re Swartz,* 232 F.3d 862, 863, 56 U.S.P.Q.2d 1703, 1704 (Fed. Cir. 2000); *In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995) (citing *In re Bundy*, 642 F.2d 430, 433, 209 U.S.P.Q. 48, 51 (C.C.P.A. 1981)). 462, 108 U.S.P.Q. 321, 325 (C.C.P.A. 1956). Furthermore, Applicants do not have to provide evidence sufficient to establish that an asserted utility is true "beyond a reasonable doubt." *In re Irons,* 340 F.2d 974, 978, 144 U.S.P.Q. 351, 354 (C.C.P.A. 1965). Instead, evidence will be sufficient if, considered as a whole, it leads a person of ordinary skill in the art to conclude that the asserted utility is more likely than not true. MPEP § 2164.07. Applicants have met this burden.

Credibility has still not been assessed. Credibility is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 752 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the

disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The Examiner "must do more than merely question – [he] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); M.P.E.P. § 706.03(a)(1) ("Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided..."). Here the Examiner has not even attempted to meet this burden. Thus, the lack of challenge of utilities suggests that no proper rejection has been made.

In view of the above, Applicants maintain that the claimed nucleic acid molecules are supported by credible, specific and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claims 1 and 23-24 is improper. Applicants respectfully request reconsideration and withdrawal of this rejection.

***B. Rejection Under 35 U.S.C. § 112, 1st Paragraph: Enablement***

The Examiner has rejected claims 1 and 23-28 as not being enabled by the specification, because the claimed invention allegedly lacks utility. Office Action at page 5. Claims 25-28 have been cancelled without prejudice to or disclaimer of the underlying subject matter, so Applicants will respond to the rejection only as it pertains to claims 1 and 23-24. Applicants respectfully disagree and assert that the rejection has been over-

come by the foregoing arguments regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph is improper. Reconsideration and withdrawal are respectfully requested.

***3. Rejections under 35 U.S.C. § 102***

***A. Rejection under 35 U.S.C. § 102(b) to Matsuoka, et al.***

Claims 1 and 23-28 stand rejected under 35 U.S.C. § 102(b) as allegedly being "clearly anticipated by Matsuoka et al. [J. Biochem. 102:673 (1987)]." Office Action at page 6. Claims 25-28 have been cancelled without prejudice to or disclaimer of the underlying subject matter, so Applicants will respond to the rejection only as it pertains to claims 1 and 23-24. Applicants respectfully traverse this rejection.

The Examiner asserts that "Matsuoka et al. reveals that the query match percent identity is 96.3%" and that the reference "discloses the cDNA via its sequence as encoding ribulose - 1,5-bisphosphate carboxylase." Office Action at page 6. "It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986). Further, "an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device." *In re Donohue*, 766 F.2d 531, 226 U.S.P.Q. 619 (Fed. Cir. 1985). In the present application, claim 1, as amended, is directed to an isolated nucleic acid molecule that encodes ribulose bisphosphate carboxylase enzyme, where the nucleic acid molecule comprises the sequence of SEQ ID NO:5 or complete complement thereof. Claims 23 and 24 are directed to a substantially purified nucleic acid molecule comprising or consisting of the

nucleic acid sequence of SEQ ID NO:5. Whatever else Matsuoka *et al.* discloses, it does not disclose a nucleic acid molecule that encodes ribulose bisphosphate carboxylase enzyme, where the nucleic acid molecule comprises the sequence of SEQ ID NO:5 or complete complement thereof. As such, the presently amended claims are not anticipated by Matsuoka *et al.* cited by the Examiner. Absent a teaching of each and every element of the claim, the reference cited by the Examiner does not anticipate claims 1 and 23-24, and the rejection should be withdrawn.

Accordingly, for at least the foregoing reasons, the rejection of claims 1 and 23-24 under 35 U.S.C. § 102(b) is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

***B. Rejection under 35 U.S.C. § 102(b) to the 1990 Sigma Catalog.***

Claims 1 and 23-28 stand rejected under 35 U.S.C. § 102(b) as allegedly being "clearly anticipated by the 1990 Sigma Chemical Catalog disclosure of either of products O 4128, O 8628, or O 8878." (Sigma). Claims 25-28 have been cancelled without prejudice to or disclaimer of the underlying subject matter, so Applicants will respond to the rejection only as it pertains to claims 1 and 23-24. Applicants respectfully traverse this rejection.

As discussed above, "[i]t is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986). Further, "an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device." *In re Donohue*, 766 F.2d 531, 226 U.S.P.Q. 619 (Fed. Cir.

1985). In the present application, claim 1, as amended, is directed to an isolated nucleic acid molecule that encodes ribulose bisphosphate carboxylase enzyme, where the nucleic acid molecule comprises the sequence of SEQ ID NO:5 or complete complement thereof. Claims 23 and 24 are directed to a substantially purified nucleic acid molecule comprising or consisting of the nucleic acid sequence of SEQ ID NO:5. Whatever else the Sigma catalog discloses, it does not disclose a nucleic acid molecule that encodes ribulose bisphosphate enzyme, where the nucleic acid molecule comprises the sequence of SEQ ID NO:5 or complete complement thereof. The Examiner has applied an untenable interpretation of the claims to cover small fragments of the specifically claimed nucleic acid molecule and thus concludes that the claim is anticipated by the cited reference. Office Action at page 7. A grammatically consistent interpretation of claim 1, as amended, would relate the phrase "or fragment thereof" back to the phrase "ribulose-bisphosphate carboxylase enzyme" directly preceding it. Although Applicants maintain their disagreement of the Examiner's interpretation of "fragment thereof," to facilitate prosecution, the claim 1 has been amended to delete the recitation of "fragment thereof."

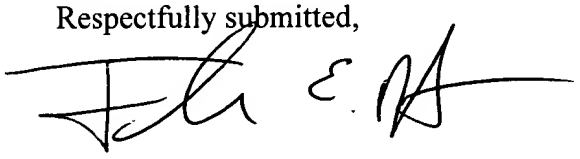
As such, the presently amended claims are not anticipated by Sigma cited by the Examiner. Whatever Sigma teaches, it does not disclose a nucleic acid molecule that encodes ribulose-bisphosphate carboxylase enzyme or SEQ ID NO:5. Absent a teaching of each and every element of the claim, the reference cited by the Examiner does not anticipate claims 1 and 23-24, and the rejection should be reversed.

Accordingly, for at least the foregoing reasons, the rejection of claims 1 and 23-24 under 35 U.S.C. § 102(b) is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

**Conclusion**

In view of the foregoing remarks, Applicants respectfully submit that the present application is now in condition for allowance, and notice of such is respectfully requested. The Examiner is encouraged to contact the undersigned should any additional information be necessary for allowance.

Respectfully submitted,



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